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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/528,989	03/20/2000	Jean Marie Vogel	9676-292	6000

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
02/27/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/528,989	VOGEL ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7,8,11-20,52,53 and 56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7,8,11-20,52,53 and 56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 31, 2007 has been entered.

Claim Rejections 35 U.S.C. 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-4, 7, 8, 11-20 and 52, 53 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boschetti et al. (US 5,635,215, IDS), in view of Bley et al. (EP 0 811 373, IDS), and Zaepffel (WO 89/087455).

3. Boschetti et al. teaches the spherical particles herein and suspension composition comprising the same used for injection into tissue. The particles are made of hydrophilic acrylic co-polymer, and in preferred embodiment, with about 10% of bifunctional monomer. The particle sizes are range from 10 μm to 2000 μm. specific ranges of particle size within the range of 10 μm to 2000 μm are disclosed. See, particularly, the examples 1-21. The particles may be incorporated with other agents, such as dye, magnetic resonance imaging agent, or contrasting agent. The particles may also carry cell adhesion promoter. See, columns 3, lines 16-36, and the claims.

4. Boschetti et al. do not expressly disclose the polymer is anionic polymer, and the particular functions as herein recited. Boschetti also fails to expressly disclose the composition would be injectable through needles of about 26 to 18 gauge, or the particular amount of the particles in the composition, or the other particular agents in the composition as recited herein.

However, Bley et al. teaches the employment of hydrophilic, insoluble, but swellable, polymeric particles for injection into tissue. See, particularly, the abstract, and the examples. Zaepffel teaches crosslinked hydrophilic copolymers of sodium acrylate and vinyl alcohol, which is insoluble and swellable, and are particularly suitable for various medical uses, see, particularly, the abstract, and page 2 of the English translation. Zaepffel further disclosed that the polymer may uptake substantial amount of water. See, page 1 the last three paragraphs of the English translation.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to use anionic polymer as the hydrophilic polymer, such as copolymer of sodium acrylate and vinyl alcohol, and to adjust the particle size within the disclosed range so that the composition would be suitable for injection with any needle required in the method.

5. A person of ordinary skill in the art would have been motivated to use anionic polymer as the hydrophilic polymer, such as polyacrylic acid salt, and adjust the particle size within the disclosed range so that the composition would be suitable for injection with any needle required in the method because it is disclosed that the composition should be injectable and acrylic polymer are known to be useful in the application. Anionic acrylic polymers are one of the three subgenus within the genus of acrylic polymers (the other two are neutral and cationic), and is

particularly known for medical use. Furthermore, crosslinked hydrophilic polymer is known to be insoluble and swellable. It is noted that Boschetti et al. prefer neutral or cationic polymers (col. 2, lines 11-16), but claim 1 encompasses all hydrophilic acrylic copolymers. It is well-settled that "Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971)." Note Further, employment of suitable carrier for an injectable composition, such as saline solution, would have been obvious to one of ordinary skill in the art because saline is a well-known biocompatible carrier. Further, the incorporation of other well-known therapeutical agents, such as anti-inflammatory agents, or cells, with the particle would have been obvious since the other agents are known to be useful as therapeutical agents. As to the functional limitations, such as "swellable," "wherein the polymer can increase its weight by at least about 20 times its original dry weight upon contacting water", the examiner notes that since the reference teaches, or suggests all the limitations other than the functional properties, the polymer composition as suggested by the reference would reasonably be expected to have the same properties as herein claimed. Indeed, Zaepffel discloses that copolymers of sodium acrylate and vinyl alcohol may take up substantial amounts of water.

Further, a person of ordinary skill in the art would have been motivated to use the sodium acrylate vinyl alcohol copolymers as the hydrophilic acrylic polymer because hydrophilic acrylic polymers are generally known to be useful, and sodium acrylate vinyl alcohol copolymers is particularly known as hydrophilic polymer useful for medical purpose. The employment of the copolymer is seen to be a selection from amongst equally suitable material and as such obvious. Ex parte Winters 11 USPQ 2nd 1387 (at 1388).

Response to the Arguments

Applicants' remarks submitted October 31, 2007 have been fully considered, but are not persuasive.

Applicants' remarks are essentially moot in view of the new ground of rejection. The new references added to the rejections provide further evidence that the recited function of properties, such as water absorption, and swellability, of hydrophilic polymers are well recognized properties of hydrophilic polymers in the art and are optimizable parameters affecting the polymer's properties. Further, the references provide evidence that sodium acrylate-vinyl alcohol copolymer is well-known hydrophilic polymer suitable for various medical utilities. Therefore, making a composition comprising particles of the polymer suitable for injection would have been obvious.

Applicants contend that

Boschetti teaches that one problem to avoid is that some types agents cause "sticking of catheters" (col. l, lines 31-34) or "blocking of the systems necessary for injection" (col. 6, lines 49-52), one of skill in the art, upon reading Boschetti, may consider avoiding the use of certain swellable compositions, especially those that swell by at least about 20 times the original dry weight upon contacting water, in order to avoid potential problems such as needle clogging or sticking. Thus, the Applicants maintain that Boschetti actually teaches away from the instant invention.

The arguments are untenable. Applicants attention is directed to Bley et al., where it is disclosed that with proper carrier, hydrophilic polymers are not hydrated, all swelled, before the injection. See, the abstract, col. 5, lines 1-21. Further, bother Boschetti et al. and Zaepffel teaches the hydrophilic particle are injectable and/or swellable, there is no conflict for a particles being injectable and being swellable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shengjun Wang
Primary Examiner
Art Unit 1617